Amendment in Response to July 12, 2005 Office Action Application No. 10/810,535 Docket No. 7226-207

Remarks

A. Summary of the interview with the Examiner on November 3, 2005

Applicants extend their appreciation for the time and opportunity granted by the Examiner to discuss the outstanding issues regarding this application.

During the course of the interview, Applicants provided a sample of an embodiment of the invention to demonstrate its elasticity and use to provide compression for body support. Applicants used the sample of the embodiment of the invention to demonstrate how the invention differs from the prior art. It is respectfully submitted that the prior art did not show the stretchability of Applicants' invention without resulting in breakage of the gel layer. Applicants also explained to the Examiner that the prior art references cited by the Examiner relate to surgical dressings, and as such, are not designed nor intended to provide such support for a body part. Applicants' invention, on the other hand, is a wrap and it is intended and designed to provide compression for body support. It is respectfully submitted that Applicants' invention is structurally different from the prior art. Applicants then discussed the prior art cited in the pending Office Action:

1. Pocknell '574

Pocknell's invention is a surgical dressing for treatment of burns. Pocknell describes the silicone gel as soft and frangible. In consequence, a support material is added to improve the strength and ease of handling of the gel (col. 1, lines 47-52). The support described in Pocknell is provided for the gel itself. There is no teaching or suggestion that it is added to provide stretchability or compression to support a body part. In addition, the elastomer film disclosed in Pocknell is too thin to provide compression for support to a body part since it "preferably has a thickness of from about 0.01 cm to about 0.1cm. Thinner films can be employed but are more difficult to fabricate" (col. 2, lines 33-40). Moreover, Pocknell states that "thicker films reduce the ability of the gel to conform to the body contour and offer no compensating advantage" (col. 2, lines 38-40). Therefore, it is respectfully submitted that Pocknell teaches away from providing compression to support a body part. Moreover, as demonstrated by a sample of Pocknell's dressing at the interview, it will lose shape and break if stretched.

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2. Fabo '076

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Fabo's '076 invention is a hypertrophic wound dressing. It is respectfully submitted that the carrier is too thin to be "capable of elasticity sufficient to provide compression against a body surface" as claimed by Applicants: "The carrier material has a thickness of 0.03-1mm, preferably 0.05-0.1mm, and a surface weight of 15-150 g/m2, preferably 0.0525-50 g/m2, and is comprised either of nonwoven material, a knitted or woven textile material or of perforated plastic film" (col. 2, lines 30-35). In addition, Fabo '076 states that "the silicone-gel also functions as a means for securing the dressing in place whilst worn. The adhesive strength of the silicone-gel has been adapted to this end, so that the adhesive strength will be sufficiently great to hold the dressing securely in place even when the dressing is subjected to the results of body movements and friction against the skin" (col. 3, lines 8-15). Fabo's '076 invention relies on the adhesive strength of the silicone gel to hold the "dressing" in place and, thus, provides no compression for support. In contrast, Applicants' invention does not rely upon the gel but, rather, provides a stretchable laminate wrap formed of the gel and an elastic carrier providing compression as it is wrapped around and stretched over a body surface. The foregoing was demonstrated with a sample of Fabo's '076 dressing at the interview.

3. Fabo '363

Fabo's '363 invention is a wound dressing. It is hydrophobic and porous, for use on exuding wounds. The carrier is not capable of elasticity sufficient to provide compression against a body surface. It is a mere "reinforcement" for the gel layer (col. 2, lines 4-8, lines 27-31, line 36) in the form of a "knitted network" (Figure 1 and col. 2, lines 27-31). While the carrier may provide support to the gel, there is no teaching or suggestion that it provides compression support for the body part. Fabo's '363 invention also relies on the tackiness of the silicone gel for self-adherence (col. 3, lines 12-14) and does not teach or suggest wrapping to provide adherence and support through compression. A sample of Fabo's '363 dressing was shown to the Examiner to illustrate the foregoing arguments.

4. <u>Docter '946</u>

Docter's invention is a therapeutic mat. Docter uses a hydrogel (col. 2, lines 26 and 42-43), in contrast to Applicants' invention which uses a hydrophobic gel. Applicants showed a sample of a

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hydrogel to the Examiner during the interview. Hydrogels seep easily when wet (e.g. by sweat or exudate).

In Docter, a carrier is added to hold and keep the hydrogel from seeping, not to provide compression against a body surface. The carrier in Docter is a "slightly elastic substrate" (col. 2, line 25), "preferably made of a fabric material, such as a spandex material" (col. 2, lines 32-33), "of sufficient strength and inelasticity to maintain the gel 14 in a relatively fixed position" (col. 2, lines 37-39). There would be no motivation to use the carrier in Docter for compression since ,as Docter states, "The substrate 12 should have sufficient elasticity to accommodate expansion which occurs during the absorption of the fluids in the hydrogel 14" (col. 2, lines 34-37). Thus, rather than providing compression as in the present invention, Docter allows for expansion and, in fact, teaches away from Applicants' invention.

Docter also does not disclose that the carrier is the loop portion of a hook and loop fastener. It is clearly indicated that the hook and loop portions 18 are localized to the ends of the straps only. Despite the fact that Docter used hook and loop fasteners in his invention, he only used them to clasp (i.e. for their known use).

Docter's invention as described also does not provide musculo-skeletal support as recited in dependent claims 36-39. The carrier is not strong enough to provide support to the <u>muscle and bone (i.e. "musculo-skeletal" support)</u>. Merely keeping a wrap in place is not equivalent to providing compression for musculo-skeletal support, which Applicants' invention provides, as the Examiner was able to appreciate by direct inspection of an embodiment of the invention.

For the foregoing reasons, Docter does not teach how to make a laminate wrap comprising a silicone gel laminated to the elastic loop portion of a hook and loop fastener so that it is capable of elasticity sufficient to provide compression against a body surface without substantial fragmentation. In addition, there would have been no motivation to combine the foregoing references, for the reason, *inter alia*, that none of the inventors disclosed an intention of using their inventions to provide compression for support to a body part.

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The prior art references cited by the Examiner disclose dressings, which are not capable of elasticity sufficient to provide compression for support to a body part. Moreover, none of them use the

loop portion of a hook and loop fastener as a carrier.

The claimed elastic modulus of about 50% was also discussed. The stretchability of the carrier

contributes to its capacity to provide compression against a body surface by virtue of the pulling force it

allows to create. However, none of the prior art references intended to provide any compression for body

support. Therefore, there would have been no motivation to test the elasticity modulus of the carriers and

claim the 50% modulus as previously suggested in the prior Office Action.

Applicants have been the first at inventing a stretchable laminate of a silicone gel layer and a

carrier which does not result in breakage of the gel layer when stretched. As a result, Applicants'

invention can be used to apply adjustable pressure therapy to the body while simultaneously providing

silicone therapy for the skin.

Following the inspection of the sample of an embodiment of the invention, and the demonstration

of its distinction from the prior art, the Examiner proposed to amend the claims with substitute language

which may be more suitable to define the invention.

B. Amendment

It is respectfully submitted that notwithstanding that Applicants sustain that they have been the

first to invent a composite material of such elasticity, and compression to provide body support, coupled

with the skin therapy associated with the gel, and maintain the arguments presented in previous

amendments, Applicants have amended the claims to provide alternate language, considering that it may

be more suitable to define the invention.

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C. Closing

Claims 1, 3, 5, 28-29, 31-32 and 36-39 have been amended. Claims 1, 3, 5, 28-29, 31-32 and 36-39 are now pending and believed to be in condition for allowance. Applicant respectfully requests that all pending claims be allowed.

Please apply any credits or excess charges to our deposit account number 50-0521.

Date: 12/21/05

Isabel Cantallops

Registration No. 57,710

Respectfully submitted,

Customer No. 27383

Telephone: (212) 895-1376